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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,853	02/09/2007	Gen-Ichiro Soma	80246(302741)	9265
21874 7590 04/16/2009 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER MI, QIUWEN	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 04/16/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,853	<b>Applicant(s)</b> SOMA ET AL.	
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-14, 16-22, 26-29 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-14, 16-22, 26-29 and 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/22/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **CONTINUED EXAMINATIONS**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/09 has been entered.

Applicant's amendment in the reply filed on 1/29/09 is acknowledged, with the cancellation of Claims 1-11, 15, 23-25, and 30-32. Claims 12-14, 16-22, 26-29, and 33-38 are pending. **Claims 12-14, 16-22, 26-29, and 33-38 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

### **Specification Objections**

The disclosure is objected to because of the following informalities: The specification recites "novel" on pages 25 and 34. It is suggested that the term "novel" be deleted from the language of the specification. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel or new, since the scope of the invention no longer embraces what is considered "novel". Thus, the incorporation of the term "novel" into the language of the specification is not appropriate. Correction is required.

**Claim Rejections –35 USC § 112, 2<sup>nd</sup>**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-14, 16-22, 26-29, and 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites “A fermented plant extract obtained by the method for fermentation and culture comprising: fermenting a material derived from an edible plant and containing a glucide whose major component is a polysaccharide with a facultative anaerobic gram-negative bacterium which lives in a symbiotic relationship exclusively with a plant and simultaneously culturing said facultative anaerobic gram-negative bacterium in a medium containing no component derived from an animal”. The recitation of Claim 12 is very confusing, and it is not clear exactly what Applicant is claiming for.

First of all, Claim 12 recites the limitation "the method" in line 2, and there is insufficient antecedent basis for this limitation in the claim. Secondly, claim 12, line 2 recites “comprising”, and it is not clear what subject “comprising” has. Is it “a fermented plant extract comprising” or “culture comprising”? Thirdly, it is uncertain what subject "containing" (in line 3) has. Is it "an edible plant containing", “culturing containing”, or “a fermented plant extract containing”? Further more, it is not clear who is "with a facultative anaerobic gram-negative bacterium" (in line 3), does it refer to “an edible plant”, or "a polysaccharide”?

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For the same reason, Claims 26, and 33 are very confusing too.

Claim 16 recites "The fermented plant extract according to claim 12 exhibits physicochemical properties which are an ability of microphage activation even with the presence of polymyxin B". First of all, claim 16 recites the limitation "the presence" in lines 2-3, and there is insufficient antecedent basis for this limitation in the claims. Secondly, "properties which are an ability" is grammatically incorrect.

Claim 26 recites the limitation "the method" in line 1, and there is insufficient antecedent basis for this limitation in the claims.

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

In order to prosecute the examination, Claim 12 is construed as "A fermented plant extract obtained by fermenting an edible plant in a medium containing no component derived from an animal, said plant contains a glucide whose major component is a polysaccharide, and said plant lives symbiotically with a facultative anaerobic gram-negative bacterium".

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-14, 16-22, 26-29, and 33-38 are rejected under 35 USC § 102 (b) as being anticipated by Soma et al (US 5,494,819), as evidenced by Inagawa et al (Homeostasis as regulated by activated macrophage. II. LPS of plant origin other than wheat flour and their concomitant bacteria, Chem. Pharm. Bull. 40 (4) 994-997, 1992)\*.

Soma et al teach three glucose-fermentative gram-negative small bacilli which produce lipopolysaccharide (LPSs) (col 1, lines 12-15). The three bacterial according to the present invention were isolated from all kinds of wheat produced in any place and its processed goods (col 3, lines 10-16). Soma et al also teach in a 50 ml coning tube, there was charged 1.04 g of hard flour containing 1.09% of ash followed by addition of 20 ml of distilled water therto to prepare a 50 mg/ml aqueous solution of wheat flour (thus a fermented edible plant extract). The solution was cultured in a water bath at 37°C for 0, 1, 2, 3, 4, 6, 8, 10, 12, 20, 24, and 45 hours (col 5, lines 46-55) (thus fermented, thus contains no component derived from an animal). Soma et al also teach the colony formation from and isolation of *Pantoea agglomerans* from aqueous solution of wheat flour (throughout the document). Thus the pure culture *Pantoea agglomerans* is the fermented extract from edible plant wheat, and therefore the fermented plant extract. Soma et al further teach a pure culture of *Pantoea agglomerans* (thus facultative anaerobic gram-negative bacterium, bacillus) which produces lipopolysaccharides (col 1, 7-13), and it may be used in food (thus a food containing the fermented plant extract, thus the limitation of claims 18

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and 21 is met), drinks and feed (col 5, lines 10-15), it has excellent immunity-stimulating (thus the fermented plant extract has an immunopotential activity, thus the limitation of claim 17 is met), analgesic and antiwithdrawal effects show a high therapeutical range, and may be provided at a low cost and in a large amount (col 2, lines 50-55). At last, Soma et al teach any of the above preparations (thus a pharmaceutical, thus the limitation of claim 14 and 20 is met) including immunity stimulators may be produced conventionally. For example, in the conventional manner of preparing medicines (thus a composition, a pharmaceutical) or veterinary medicines, they may be supplied conventionally in the form of powders (thus a fermented plant extract powder, thus the limitation of claims 13, 27, 34, 36, and 38 is met), granules, pills, tablets, troches, capsules, solutions, pastes, ointments, liniments, lotions (thus a bath agent containing the fermented plant extract, thus the limitation of claims 19 and 22 is met), suppositories, injections, etc (col 5, lines 12-18).

As evidenced by Inagawa et al, lipopolysaccharide (LPS) of plant origin other than that of wheat flour was surveyed. Concomitant bacteria possibly extracting in root of farm products can be considered to contribute of LPS of plant origin. Some LPS were derived from concomitant bacteria which had probably come from root. Three predominant bacteria have been isolated and identified; *Pantoea agglomerans*, *Enterobacter cloacae* and *Serratia ficaria*. These LPSs were purified and their chemical compositions were examined (see Abstract). *Pantoea agglomerans* is the most remarkable, since it accounts for 40-70% of all living bacteria in wheat bran and wheat flour and is persistently isolated from all kinds of wheat flour produced in districts as different as, Canada, USA, Australia and Japan (page 996, 2nd column, last column). Inagawa et al also teach, *Pantoea agglomerans* is a species of gram-negative soil bacterial

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ubiquitously distributed, especially in cotton-seed and wheat, and contributes to the growth of plant by nitrogen fixation and also by release of phosphorus (page 997, 1st column, 1st paragraph) (thus lives in a symbiotic relationship exclusively with a plant).

Therefore, the aqueous solution of wheat flour culture in Soma et al inherently contains the symbiotic gram-negative soil bacterial *Pantoea agglomerans*, and “facultative anerobic” is the intrinsic properties of the bacteria.

It is noted that since the cited reference teaches the claimed fermented plant extract, it is deemed that the fermented plant extract would inherently have macrophage activation ability even with the presence of polymyxin B (thus the limitation of claim 16 is met).

Therefore, the reference is deemed to anticipate the instant claim above.

\*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655